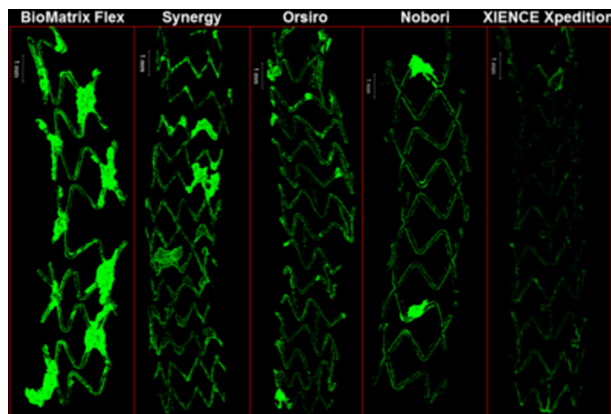


least in XIENCE with significant difference compared to BioMatrix Flex ( $p < 0.001$ ) and Synergy ( $p < 0.001$ ).

**Conclusions:** The current ex vivo swine shunt model demonstrated the least thrombogenicity in permanent polymer XIENCE as compared to 4 biodegradable polymer DES, which emphasizes its acute protective effect against thrombus formation.



#### TCT-437

##### Transcatheter vs surgical mitral annuloplasty: computational analysis of the biomechanical impact

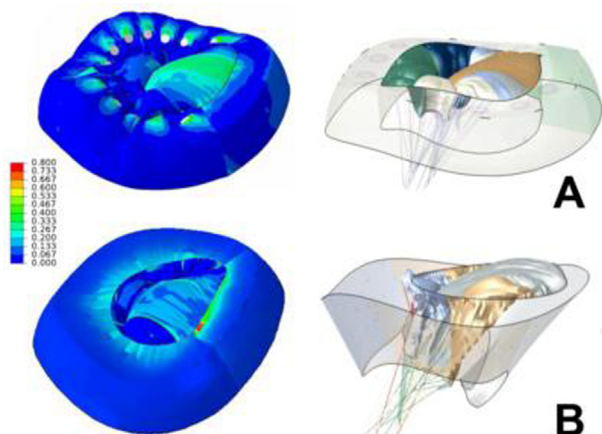
Marco Stevanella<sup>1</sup>, Alberto Redaelli<sup>1</sup>, Tal Reich<sup>2</sup>, Andrea Guidotti<sup>3</sup>

<sup>1</sup>Politecnico di Milano, Milan, Italy, <sup>2</sup>Valtech Cardio, Or Yehuda, Israel, <sup>3</sup>University Hospital of Zurich, Zurich, Switzerland

**Background:** Transcatheter mitral annuloplasty (TMA) has been introduced as alternative to open-heart surgery. The Cardioband TMA (Valtech Cardio, Israel) is a flexible band delivered over the posterior annulus by multiple anchors. The implant size is adjusted to reduce the annulus dimension. The aim of the study is to compare the biomechanical impact of the Cardioband TMA vs. a surgical annuloplasty procedure (SAP) with a rigid-complete ring.

**Methods:** A computational model of pathological functional mitral valve (MV) was derived from cardiac MRI, to analyse effects during systolic closure following TMA and SAP. The TMA was simulated by placing 14 anchors (8mm spacing) in the posterior annulus, as per device specifications. An homogeneous 33% shortening of the device was imposed, as from clinical data. The SAP was simulated modelling the annulus into the surgical ring shape. Closure dynamics, leaflets and annular configuration and stresses were compared.

**Results:** MV area was reduced from 16.0 to 7.8 and 6.5cm<sup>2</sup> with TMA and SAP, respectively. Coaptation length (CL) increased from 0 to 3.5 and 4.3mm respectively. Leaflet and the annular peak stresses at baseline were both equal to 800kPa. Following TMA they decreased to 250 and 500kPa, while following SAP leaflet stresses decreased to 450kPa but annular stresses increased over 800kPa.



**Conclusions:** SAP was associated with slightly higher CL and reduced MV area, but induced higher stresses on the mitral annulus. TMA resulted in an effective improvement of valve competence while avoiding mechanical overloads. These promising outcomes are under further clinical evaluation.

#### TCT-438

##### Acute and chronic effects of cryotherapy on atherosclerotic plaque composition in the thoracic aorta of cholesterol-fed rabbits: a potential solution for treatment of plaques

Stefan Verheye<sup>1</sup>, Guido De Meyer<sup>2</sup>, Lynn Roth<sup>1</sup>, John Yianni<sup>4</sup>, Maurice Buchbinder<sup>5</sup>

<sup>1</sup>Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, Antwerp, Belgium, <sup>2</sup>University of Antwerp, Antwerp, Belgium, <sup>3</sup>University of Antwerp, Antwerp, Belgium, <sup>4</sup>CryoTherapeutics, Cologne, Germany, <sup>5</sup>Foundation for cardiovascular medicine /Morristown Medical Center, San Diego, United States

**Background:** Atherosclerotic plaque rupture remains the leading cause of acute cardiovascular syndromes and the need for plaque stabilizing interventions is high. In the last 10 years, cryotherapy was investigated as a new technology to treat vascular disease. Previous studies focused mainly on treatment and prevention of restenosis in peripheral arterial disease. The efficiency of cryotherapy on stabilizing atherosclerotic plaques has never been described. The purpose of the present study was to evaluate the effect of catheter-based cryotherapy on atherosclerotic plaque composition in a rabbit model of atherosclerosis.

**Methods:** Twenty-four New-Zealand White rabbits were fed a 0.3%-cholesterol supplemented diet for 24 weeks. At three predefined sites of the atherosclerotic thoracic aorta, balloon angioplasty applying either single dose, double dose cryotherapy or control inflation was performed. Rabbits were continued on cholesterol-supplemented diet for 1 day (acute) or 4 weeks (chronic). After euthanasia and preparation for histology, sections were analyzed for apoptosis, content of smooth muscle cells (SMC), collagen, and macrophages, endothelium and calcifications.

**Results:** One day after cryotherapy, apoptotic cell death of SMCs and endothelial cells (ECs) was observed, whereas macrophages were unaffected. Four weeks after cryo-treatment, the amount of SMCs was restored and the EC layer was regenerated. Moreover, the thickness and type I collagen content of the fibrous cap was increased, indicative of a more stable plaque. The percentage of macrophages was slightly increased in deep layers, but unaltered in luminal layers of the plaque. The frequency of plaque calcifications was increased and signs of positive remodeling were observed.

**Conclusions:** For the first time in atherosclerotic lesions, this present study demonstrated that cryotherapy is safe and appears to stabilize atherosclerotic plaques in a rabbit model. This warrants further investigation.

#### TCT-439

##### Assessment of Biocompatibility of the Multilayer Flow Modulator with Varying Thread Numbers

Sherif Sultan<sup>1</sup>, Michel Bonneau<sup>2</sup>, Edel P. Kavanagh<sup>1</sup>, Chantal Kang<sup>2</sup>, Antoine Alves<sup>3</sup>, Niamh Hynes<sup>1</sup>

<sup>1</sup>Western Vascular Institute, Galway, Ireland, <sup>2</sup>Centre de Recherche en Imagerie Interventionnelle (CR2i), Jouy-en-Josas, France, <sup>3</sup>NAMSA, Chasse-sur-Rhône, France

**Background:** The Multilayer Flow Modulator (MFM) (Cardiatis, Isnes, Belgium) is a self-expandable mesh of cobalt alloy wires used for the treatment of aortic aneurysms. We assessed the impact of design thread count and duration of implantation on the biocompatibility of the MFM in porcine animal models.

**Methods:** Eight mini-piglets received 26 MFM (12 with 56 thread design, 14 with 80 or 96 threads) in iliac, carotid, and renal arteries. Animals were sacrificed/explanted at 1, 3, and 6 months, when histological and ultrastructural analyses were conducted.

**Results:** The MFM was successfully deployed in 25 of 26 cases. Percentage stenosis was  $16.9\% \pm 5.1\%$  for the 56 thread devices versus  $33.4\% \pm 10.2\%$  for the 80-96 thread devices ( $p = 0.001$ ) at 3 months, and  $21.7\% \pm 9.9\%$  for the 56 thread devices versus  $33.6\% \pm 12.4\%$  for the 80-96 thread devices ( $p = 0.004$ ) at 6 months. The 5 devices selected for SEM examination were well deployed, integrated into the vessel wall and endothelialized (Figure 1), and had patent side branches.